K092639

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: 2009-August-25

DEC - 2 2009

Submitter: GE Healthcare, GE Medical Systems, SCS
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Device: Trade Name: Innova Vision Applications

Common/Usual Name: Innova Vision, Innova TrackVision and Innova EP Vision

Classification Names: Picture archiving and communications system

Product Code: LLZ 21CFR 892.2050

Predicate Devices: Manufactured by GE Medical Systems:

- K852353 DG 200/300 Digital Angiographic System
- K092004 Innova 4100 IQ, 3100IQ, 2100IQ with StentViz
- K052995 Advantage Workstation
- K041521 Volume Viewer plus

Manufactured by Philips:

- K062650 EP-Navigator

Device Description: *Innova Vision Applications* image processing algorithms are executed on a commercially available hardware platform called AW *(Advantage Workstation)*, which can perform the following functions:

- Superimpose the segmented DICOM 3D XA, CT, MR dataset on radioscopic or radiographic image of the same anatomy, obtained on an *Innova* Fluoroscopic X-ray system
- Register the segmented DICOM 3D XA, CT, MR data with radioscopic or radiographic images obtained on an *Innova* Fluoroscopic X-ray system for interventional procedures.

The *Innova Vision Applications* software will be available as three different options (Innova Vision, TrackVision and EP Vision) that target different clinical indications: catheter-based interventions for interventional procedures such as neuroradiology or interventional radiology; needle-based interventions for interventional radiology; and interventional cardiology procedures such as electro-physiology procedures, respectively.

Each option contains specific functions and settings and supports 3D datasets from specific modalities.

Innova EP Vision provides image stabilization features such as ECG gated display or motion tracking in the image.

To enhance guidance capabilities, the *Innova Vision Applications* software can load planning data, deposited on the 3D model in *Volume Viewer*, such as 3D landmarks, ablations lines or trajectories for needle path, and display them on the 3D-2D fused image to support the physician during procedures. The application also allows marking points of interest such as ablation points during the procedures.

To provide efficient workflow during the interventional procedures, the most frequently used functions can be controlled from tableside.

Intended Use: Innova Vision Applications software is intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Technology: Innova Vision Applications software is a software application that executes on the Advantage Workstation (AW) review station. The live Innova fluoroscopic images, as well as the necessary exam data, are transmitted from the Innova Digital Fluoroscopic Imaging System to the Advantage Workstation (AW) through a dedicated link. The 3D datasets are loaded from the AW database. The application saves fused photos or video clips in this database.

The 3D-2D fusion and the user interface of the application are displayed on the AW main screen, which is distributed in Control Room and in Exam Room by a video splitter.

The most frequently used functions are available from exam room on the Innova Central Touch Screen. This user interface is controlled by the application through the Innova Ethernet network.

The Innova Vision Applications employs the same fundamental scientific technology as its predicate devices.

Test Summary

Summary of Non-Clinical Tests:

The Innova Vision Applications Software comply with voluntary standards IEC60601-1-4 (2000): Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, edition 1.1. (General) and IEC62304 edition 1 (2006): Medical device software - Software life cycle processes.

The following quality assurance measures were applied to the development of the system:

- Risk Management
- Requirements Reviews
- Design Reviews
- Software Unit Testing (Unit Test Verification)
- Software Integration Testing (Integration Verification)
- System Testing (System Verification)
- Final acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Innova Vision Applications, did not require clinical studies to support substantial equivalence.

Determination of Substantial Equivalence: GE Healthcare believes that the Innova Vision Applications software is as safe and effective, and performs in a substantially equivalent manner to the predicate devices. This conclusion is based on:

- Innova Vision applications do not introduce new indications for use.
- Innova Vision applications do not raise new issues of safety and effectiveness.
- Innova Vision applications do not introduce new technology.

Conclusion: GE Healthcare considers the Innova Vision Applications to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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DEC - 2 2009

Re: K092639
Trade/Device Name: Innova Vision Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 18, 2009
Received: November 19, 2009

Dear Ms. Landreville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092639

Device Name: Innova Vision Applications

Indications for Use:

Innova Vision Applications software is intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Prescription Use_X_ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092639